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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,504	04/21/2004	David Epstein	23239-558A (ARC-58A)	7640
30623	7590	10/22/2010		
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C ONE FINANCIAL CENTER BOSTON, MA 02111			EXAMINER SCHNIZER, RICHARD A	
			ART UNIT	PAPER NUMBER
			1635	
			MAIL DATE	DELIVERY MODE
			10/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,504	EPSTEIN ET AL.	
	Examiner	Art Unit	
	Richard Schnizer	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/1/10.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/18/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

An amendment was received and entered on 9/1/2010.

Claims 11 and 14-16 remain pending and are under consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11 and 14-16 stand rejected under 35 U.S.C. 102(b) as being anticipated by Janjic et al (US 6,229,002, of record).

Janjic taught (SEQ ID NO: 83) which is an anti PDGF aptamer. This aptamer contains the sequence 5'GCGTT-3', conforming to the instantly recited formula "rCGyy". See Fig. 2A.

Janjic also taught a composition comprising the disclosed aptamers and an antitumor drug such as daunorubicin (see column 25, lines 26-32). Daunorubicin is an intercalating agent and so is considered to modify the structure of DNA. It is also considered to be an antimetabolite to the extent that it inhibits nucleic acid metabolism,

e.g. DNA replication. Moreover, daunorubicin is DNA modifying agent inasmuch as it can generate free radicals and cause strand breakage.

Thus Janjic taught an aptamer with the structure required by the instant claims, and so anticipates the claims.

Response to Arguments

Applicant's arguments filed 9/1/2010 have been fully considered but they are not persuasive.

Applicant asserts that Janjic taught only a first nucleic acid sequence, SEQ ID NO: 83, that binds to a first target PDGF. Applicant asserts that the 5'-GCGTT-'3 sequence within SEQ ID NO: 83 is part of the first nucleic acid sequence, and is not a second sequence that binds to a second target. This is unpersuasive. It is clear that SEQ ID NO: 83 is a first sequence of nucleotides that comprises many sequences of nucleotides inasmuch as a "sequence" need only be two nucleotides in length. Each of the many sequences comprised by SEQ ID NO: 83 may be arbitrarily referred to as a second, third, fourth, or fifth, etc. sequence. To the extent that Applicant argues that the claimed second sequence cannot be comprised within the claimed first sequence, Applicant is arguing limitations that are not in the claims.

Applicant argues that there is no disclosure in Janjic that the 5'-GCGTT-'3 sequence within SEQ ID NO: 83 would actually bind to any target other than PDGF or that it would stimulate an immune response. This is unpersuasive. Janjic taught the structure recited in the claims. The office does not have the facilities for examining and

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comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same functional characteristics as the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPAI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ2d 1922, 1923 (BPAI 1989). Applicant has not met this burden.

Applicant argues that Janjic does not teach each and every limitation of the claimed invention as arranged or combined in the claims. This is unpersuasive because the only limitations that Janjic does not explicitly teach are functional limitations that, absent evidence to the contrary, are accounted for by the structure disclosed by Janjic. Applicant's statement that "Janjic does not disclose aptamers containing CpG motifs in general" need not be assessed in view of the fact that Janjic disclosed the claimed structure. The statement that Janjic did not disclose "the specific CpG motif in applicants' claims" is incorrect as Janjic clearly disclosed a 5'-GCGTT-3' motif. As discussed above, the functional limitations associated with the claimed structure are considered to be present in the structure absent evidence to the contrary.

Finally, Applicant argues that Janjic does not inherently anticipate the claimed invention because the presence of the CpG motif in the context of SEQ ID NO: 83 alone is not dispositive of the ability of the motif to bind to a given target. This assertion is unpersuasive because it is attorney opinion that is not supported by evidence. The

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oligonucleotide of Janjic meets every structural limitation of the claims. Absent evidence to the contrary, the 5'-GCGTT-'3 sequence, which is a species of the claimed rCGyy motif, would be bound by a cellular TLR9 receptor and stimulate an immune response. See the instant specification at paragraph 187 which indicates that binding of CpG sequences by TLR9 receptors "triggers defense mechanisms leading to innate and ultimately acquired immune responses. For example, activation of TLR 9 in mice induces activation of antigen presenting cells, up regulation of MHC class I and II molecules and expression of important costimulatory molecules and cytokines including IL-12 and IL-23. This activation both directly and indirectly enhances B and T cell responses, including robust up regulation of the TH1 cytokine IFN-gamma." Absent evidence to the contrary, the 5'-GCGTT-'3 sequence within the aptamer of Janjic also possesses the functional characteristic of being able to bind toTLR9 receptors and induce an immune response. For these reasons the rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached at (571) 272-0951. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Richard Schnizer/
Primary Examiner, Art Unit 1635